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Introduction

According to stereotypes, the compliance officer for a large corporation might seem to be something like the cousin of Toby Flenderson, the sad-sack human resources director who was the butt of so many jokes in the television sitcom, *The Office*. Like Flenderson, the compliance officer might seem to be a kind of joyless drone, constantly offering monotonic reminders to the managers and other employees about the rules that they have to follow, and regularly handing out lengthy forms that need to be completed for some purpose that seems elusive to everyone but the compliance officer. If this stereotype rings true, it is probably because the process of assuring that a corporation's managers, employees, and agents comply with the law seems like a dreary adjunct to the corporation's main purpose. This stereotype begs a question: must compliance always be understood as an unfortunate chore or can it seem more engaging and important to the employees and agents of a corporation?

The stereotypical conception of compliance is reinforced by some of the fundamental assumptions about what the primary objectives of a corporation should be and about how a corporation should accomplish those objectives. According to the prevailing theory of corporate structure, a corporation exists for the sole purpose of earning profits for its shareholders, and all of its actions are to be directed toward that end. If compliance with the law is not an inherently profit-making activity, it is to be treated as a constraint on the corporation's efficient operation. According to this view, compliance will generally be considered a burden that inhibits the corporation's ability to earn profits, and it should be discouraged except to the minimum extent necessary.

This view of compliance does not always serve corporations well, however. The potential problems with the stereotypical approach to compliance are evident in the health care field, as corporations try to deal with two complicated, open-ended, and ever-evolving sets of statutes and their attendant regulations. These two statutory schemes arise from the Anti-Kickback statute and the False Claims Act ("FCA").[1] Both of these statutes can apply to many transactions in the health care field. But, because they are broadly framed, and because the details of health care transaction are often complicated and widely

continues to level the playing field in litigation. Roni can be reached at roni@|yourtcp.comor (703) 570-5264. I would like to thank the FAMU Law Review Team for their laser focus to detail. I thank my amazing better half, MGS, to be better every day.

1. 42 U.S.C. § 1320a-7b (2015); 31 U.S.C. §§ 3729-3731 (2012).

varied, it is not intuitively obvious how to make sure these rules are being followed in any particular case. If one follows the traditional approach and tries to promote compliance with these statutes by viewing compliance as an expensive burden that should be minimized as much as possible, the long-term risk of liability will be severe.

Assuring compliance with these statutes requires a new way of thinking about compliance. The traditional view of compliance as a constraint on profit-making must be replaced by a conception of compliance as a goal of the corporation, one that must be internalized and valued along with the profit-making motive. To be sure, compliance must always take a subsidiary place to profit-making as a corporate objective, but it should be viewed as a goal of corporate action, not simply as a constraint upon it. In other words, this paper will argue that corporations should stop treating regulatory compliance as a source of external costs that should be minimized, and that they should start treating regulatory compliance as a legitimate corporate interest that must be served alongside other interests.

This paper offers some suggestions about how to develop a new way of thinking about compliance in the context of health care. It begins in Part I by reviewing some of the essential conceptual approaches to corporate compliance, especially a developing concept often known as the "New Governance." As Part I shows, it is possible to think of legal compliance as conformity to a constraint imposed by an outsider or as the identification of lawful behavior as a goal to be pursued in every corporate act. Having set forth the conceptual background for compliance, Part II discusses the specifics of the Anti-Kickback statute and the FCA, as a basis for discussing how those statutes can play themselves out in the context of the health care services industry. Part III reviews a variety of different transactional circumstances in the provision of health care services, showing how the Anti-Kickback statutes and the FCA can be implicated, often subtly, in a wide variety of situations and how this implication can often lead to conflicting or confusing circumstances that can create real problems for any individual who is trying to act in both a lawful and economically efficient manner. Finally, the paper concludes by arguing that many of the insights of the New Governance approach to compliance can be profitably applied in the provision of health care services as a means of making compliance a goal of corporation action rather than a constraint upon it. Because these statutes do not present simple black-letter rules that apply uniformly, complying with them requires creative engagement on the part of corporate managers, employees, and agents; any effective compliance program must work to cultivate this engagement and

assure that individuals see themselves in a collaborative role with the compliance office.

I. Fundamental Concepts of Corporate Compliance

Corporations and other forms of enterprise organizations face a challenge in assuring that their employees conform to legal requirements, especially when those requirements are complicated.[2] One essential method for assuring lawful conduct by employees is to establish a compliance program.[3] Such programs come in a variety of forms and are shaped by a variety of different theoretical approaches.[4] Understanding the essential elements of compliance programs generally is necessary for any understanding of how health care corporations can most effectively avoid violating federal anti-kickback and anti-fraud laws.[5]

Corporate compliance programs involve a system of policies and controls that organizations implement as a means of preventing violations of law.[6] In addition, the mere existence of such programs can stand as a demonstration of corporate good-faith, which may make it easier for the corporation to distance itself from unlawful conduct by its employees.[7] Such programs often have different levels.[8] At the broadest and most general level, the programs aim to promote the overall conduct of business in accordance with prescribed legal, and increasingly ethical and cultural, norms.[9] Compliance functions undertaken by corporations and other business entities include the promulgation of behavioral codes, the institution of training programs, the identification of internal compliance personnel, and the creation of procedures and controls to ensure company-wide compliance with regulatory requirements.[10]

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2. Donald C. Langevoort, *Monitoring: The Behavioral Economics of Corporate Compliance with Law*, 2002 Colum. Bus. L. Rev. 71, 81-82 (discussing compliance programs and their principal elements).

3. *Id.*

4. *Id.*

5. *See id.*

6. *See generally id.*

7. *See generally* Langevoort, *supra* note 2.

8. *See generally* Corporate Compliance Comm., ABA Section of Bus. Law, *Corporate Compliance Survey*, 60 Bus. Law. 1759 (2005).

9. *Id.*

10. Tanina Rostain, *General Counsel in the Age of Compliance: Preliminary Findings and New Research Questions*, 21 Geo. J. Legal Ethics 465, 466-67 (2008).

Compliance programs are typically administered by a chief compliance officer who reports to executive management and is ultimately responsible for defining the elements of the program and for assuring that it is carried out.[11] Most commonly, compliance programs include both policy-making and investigatory functions.[12] In their policy-making components, compliance programs write, revise, and update corporation-wide codes of business conduct.[13] These codes specifically define what employees must do to conform to legal requirements and what is unlawful.[14] Corporate conduct codes also serve an educational function, informing employees about the legal limits on their conduct.[15] With respect to their investigatory functions, compliance programs and their administrators monitor and discipline employees to prevent or sanction employees who may breach or have breached either the corporation's own conduct policy or state or federal laws.[16]

In the most general terms, the idea of corporate compliance has both a positive and a negative aspect.[17] In positive terms, a corporation should comply with the law because its management, employees, and other agents internalize the applicable legal rules, understanding and accepting the purposes and objectives of those rules and integrating that understanding into the corporate culture.[18] In negative terms, corporate compliance means avoiding both civil and criminal liability.[19] From this negative perspective, corporations are not trying to promote or achieve the objectives behind the law; they are simply trying to avoid liability.[20] As this section will show, the greatest emphasis for compliance programs has traditionally been on the negative aspects of compliance, but there is an increasing movement toward positive ones, especially with respect to the idea that the regulators and regulated should collaborate on identifying shared goals arising from the applica-

11. *See* Rostain, *supra* note 10, at 482.
12. *See generally id.*
13. *Id.*
14. *Id.*
15. *Id.*
16. Sung Hui Kim, *Gatekeepers Inside Out*, 21 GEO. J. LEGAL ETHICS 411, 450 (2008).
17. *See generally* Lynn L. Dallas, *A Preliminary Inquiry into the Responsibility of Corporations and Their Officers and Directors for Corporate Climate: The Psychology of Enron's Demise*, 35 RUTGERS L.J. 1 (2003) (discussing the formation of corporate culture).
18. *Id.*
19. *See* Harvey L. Pitt & Karl A. Groskaufmanis, *Minimizing Corporate Civil and Criminal Liability: A Second Look at Corporate Codes of Conduct*, 78 Geo. L.J. 1559, 1599 (1990).
20. *See infra* Section II.A.

ble regulatory scheme.[21] Moreover, one useful way to understand the difference between the positive and negative aspects of compliance is to think of them as the difference between the internalization of the goals behind the law and the avoidance of external constraints.[22]

A. Compliance as Conformity With External Constraints

One way to understand compliance is to see it as conformity with a restraint imposed by an external actor.[23] According to this conception, a corporation's compliance program is an instrument for avoiding sanctions by external authorities who are engaged in an adversarial relationship with the corporation.[24] This conception begins with the premise that compliance is important because it diminishes the risk that the corporation will be punished by regulatory agencies or by the courts through civil or criminal litigation.[25]

1. "Constraint" as an External Cost

The idea of legal requirements as an external force is founded in economic theory. According to economic theory, compliance with legal rules involves an external cost, which is a theoretically unnecessary burden on the business enterprise because it does not arise from the essential aspects of the enterprise itself.[26] When government creates a legal rule for private actors, it is serving some public interest but imposing the costs of such service on a private actor.[27] Because an external cost adds inefficiency, economic theory characterizes it as something to be minimized or avoided, if possible.[28]

Under this conception of the economic effect of regulation, compliance with laws will always be contrary to the core interests of a business enterprise, and the government agencies enforcing compliance will necessarily be in an adversarial relationship with the enterprise.[29] In an adversarial relationship that often culminates in

21. *See infra* Section II.B.

22. *See infra* Sections II.A, II.B.

23. *See* Miriam Hechler Baer, *Governing Corporate Compliance*, 50 B.C. L. REV. 949, 961-62 (2009) (describing the development of corporate compliance programs as a response to the risk of the criminal prosecution of corporations).

24. Baer, *supra* note 23, at 961-62.

25. *See id.*

26. *See id.*

27. *See id.*

28. *See id.* at 961-62.

29. *See* Baer, *supra* note 23, at 979.

litigation, the parties anticipate allegations and factual and legal disputes between them; thus, a compliance program created in light of this presupposition can wind up placing as much emphasis on preparing for litigation as on preventing unlawful conduct by corporate employees.[30] Of course, avoiding liability for wrongdoing is a far different thing than promoting the utmost compliance with law, and it involves a much lower standard of conduct.[31] Consequently, when a compliance program primarily aims to insulate the corporation from liability, that corporation will aim for a much lower standard of legal—not to mention ethical—behavior by its employees.[32]

2. External Costs and Adversarial Relationships

The presupposition of an adversarial relationship between the regulators and the regulated also affects the relationship between the corporation and its employees.[33] When a compliance program is primarily focused on preparing for adjudicative outcomes, the corporation in general, and the compliance program in particular, can assume an adversarial posture of their own with respect to the corporation's employees.[34] When the corporation conceives of compliance by focusing on protecting itself from the unlawful conduct of its employees, the corporation is effectively interposing itself between the outside regulator and its employees.[35] This is particularly true when the relevant regulations come from criminal law, and the anticipated adjudication is a criminal prosecution against either the corporation itself or the employee or both.[36] If a compliance program is based on a contemplation of this result, it may provide as many incentives to cover up illegal behavior as to avoid it, and therefore it could be just as likely to promote plausible deniability for the corporation as it is to encourage employees to internalize and abide by legal requirements.[37] In the end, this kind of result could have the perverse effect of actually lowering

30. *See* Baer, *supra* note 23, at 979-80.

31. *Id.* at 961-62.

32. *Id.*

33. *Id.* at 984.

34. Baer, *supra* note 23, at 984; *see also* Robert J. Ridge & McKenzie A. Baird, *The Pendulum Swings Back: Revisiting Corporate Criminality and the Rise of Deferred Prosecution Agreements*, 33 U. DAYTON L. REV. 187, 196 (2008).

35. *See* Samuel W. Buell, *Criminal Procedure Within the Firm*, 59 STAN. L. REV. 1613, 1625-26 (2007).

36. *Id.*; *see also* Baer, *supra* note 23, at 984.

37. Baer, *supra* note 23, at 986.

the normative standards that, as a practical matter, govern employee conduct.[38]

3. The Problem of an Adversarial Approach in a Complex Organizational Environment

The potential disjunction between the corporation and its employee's points out a problem with basing a compliance program on adversarial presuppositions: Such a program does not accurately account for organizational dynamics of the corporation.[39] Not all constituents of a corporation will have precisely the same interests and motives with respect to compliance, but, the adversarial approach presupposes that they do.[40] To be sure, the conception of the corporation as a unitary entity is useful—and sometimes even necessary—in many legal contexts.[41] But, in the context of promoting compliance with the law, it can make it harder to achieve a realistic understanding of how to most effectively assure that employees follow the law.[42]

A corporation's organizational dynamics determine how its corporate culture is created and, therefore, how it disseminates information and communicates norms among its employees. Some corporations may organize horizontally through overlapping and diffuse networks; others may divide labor and information within a traditional hierarchical structure.[43] Regardless of what any corporation's particular organizational structure might be, the structure controls the flow of information through the company, and the varying nature of information flows presents varying opportunities for employees and managers to respond to legal requirements, either by complying with them or violating them.[44] In addition, any corporation's structure has important

38. Baer, *supra* note 23, at 986; *see also* Michael P. Vandenbergh, *The Private Life of Public Law*, 105 COLUM. L. REV. 2029, 2076 (2005).

39. Baer, *supra* note 23, at 986.

40. *Id.*

41. *See id.*

42. *See* Kenneth Bamberger, *Regulation as Delegation: Private Firms, Decisionmaking and Accountability in the Administrative State*, 56 DUKE L.J. 377, 382 (2006).

43. Baer, *supra* note 23, at 986; Yane Svetiev, *Antitrust Governance: The New Wave of Antitrust*, 38 LOY. U. CHI. L.J. 593, 620-21 (2007) (discussing the effect of more innovative management structures on the formation of corporate culture); *see also* Stephen M. Bainbridge, *Participatory Management Within a Theory of the Firm*, 21 J. CORP. L. 657, 669-71 (1996) (describing conventional structures of internal firm organization that affect corporate culture).

44. Donald C. Langevoort, *The Social Construction of Sarbanes-Oxley*, 105 MICH. L. REV. 1817, 1844-45 (2007) (noting that organizational structure may affect the flow of information from a corporate board and executive management and that such an information flow may determine the extent to which lower-level management and other employees com-

consequences for determining what the corporate culture will be – or even whether there will be multiple distinct corporate cultures across different subdivisions of the entity.[45] Thus, the factors that determine compliance within one subdivision of the corporation may be entirely different from those that determine compliance within another subdivision.[46] In such a complex corporate culture, the task of defining and administering a compliance program can be quite difficult.[47]

A regulatory and compliance process constructed around adversarial relationships only makes it more difficult, if not impossible, for the law to recognize such complexity.[48] Because the adversarial system ascribes liability to the corporation itself, as a unitary whole, it cannot recognize the reality of conflict or differences among different sub-units of the corporation.[49] Indeed, because the corporation's own internal structure tends to be invisible to outsiders, it is difficult for any external regulators or adjudicators to even identify differences among sub-units within the corporation.[50]

To be sure, however, adversarialism does have its uses.[51] For one thing, an adversarial relationship between the corporation and the government agency imposing regulation can help prevent the problem of regulatory capture – the circumstance in which the regulators defer to the interests of the regulated entity rather than the public interest associated with the regulation.[52] As one commentator has pointed out:

> Early in the agency's life cycle . . . [the agency's] actors maintain an adverse posture, perhaps activated by an original regulatory vision. Later on, personal career interests, interest group influence activities and the cooperative dispositions that accompany personal relationships can cause administrators' motivations to shift in a

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ply with the law); *see also* Lawrence Mitchell, *Structural Holes, CEOs, and Information Monopolies: The Missing Link in Corporate Governance*, 70 Brook. L. Rev. 1313, 1322-23 (2005) (discussing how organizational structure can affect information flows and determine which managers or employees are in a position to violate the law and how they could violate it).

45. Dallas, *supra* note 17, at 23 (noting that "[c]orporate clime is not static, but is an ongoing process. It may vary among sub-units of the corporation, although the corporation may have a dominant type").

46. Baer, *supra* note 23, at 987.

47. *Id.*

48. *Id.*

49. *Id.*

50. *See* Buell, *supra* note 35, at 1625.

51. *See* William W. Bratton, *Enron, Sarbanes-Oxley and Accounting: Rules Versus Principles Versus Rents*, 48 Vill. L. Rev. 1023, 1032 (2003).

52. *See id.*

> more accommodating direction. The regulatory mission becomes compromised as a result.[53]

Thus, without a certain level of adversarialism, regulators can lose the discipline necessary for effective enforcement and for preserving the inherent integrity of the regulatory system.[54] In short, adversarialism helps preserve a valuable degree of dynamic tension between the regulated corporation and the regulating agency, but if it is taken too far, it can lead to a disregard of factors that are important in cultivating a culture of compliance.

B. Compliance as the Realization of an Internalized Goal

Despite the dictates of economic theory, it is not essential to view the regulatory process and compliance as being antithetical to the objectives of a business enterprise.[55] Businesses need not view enforcement authorities as adversaries, and it is not essential to treat compliance costs as externalities that must be minimized.[56] It is possible to view compliance with the law as a positive value, the realization of which should be a goal for the corporation.[57] This means that compliance does not necessarily involve an adversarial relationship.[58]

Despite their prevalence in the Anglo-American legal tradition, adversarial relationships are not the only instruments for advancing legal objectives.[59] Significant recent scholarship has suggested that American institutions rely too often on adjudication and related legal strategies to accomplish social goals.[60] This critique focuses on how unintended externalities and transaction costs have undermined the liberal and democratic values that the legal system is supposed to serve.[61] As one commentator observed:

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53. Bratton, *supra* note 51.

54. *See id.*

55. IAN AYRES & JOHN BRAITHWAITE, RESPONSIVE REGULATION: TRANSCENDING THE DEREGULATION DEBATE 86-87 (1992).

56. *Id.*

57. *Id.* at 86-87.

58. *Id.*

59. *Id.*

60. *See, e.g.*, Susan Sturm, *Second Generation Employment Discrimination: A Structural Approach*, 101 COLUM. L. REV. 458, 462 (2001); Susan D. Carle, *Progressive Lawyering in Politically Distressing Times: Can New Models for Institutional Self-Reform Achieve More Effective Structural Change*, 30 HARV. J.L. & GENDER 323, 325 (2007); Timothy D. Lytton, *Using Tort Litigation to Enforce Regulatory Policy Making: Evaluating Climate Change Litigation in Light of Lessons from Gun-Industry and Clergy-Sexual-Abuse Lawsuits*, 86 TEX. L. REV. 1837, 1837 (2008).

61. Carle, *supra* note 60, at 325.

> Even at its best, litigation is expensive and time-consuming. It is surely a much better use of limited resources on all sides to devote efforts to finding creative methods for moving forward, rather than to be involved in endless gamesmanship and finger-pointing focused on what has gone wrong in the past.[62]

One alternative approach to promoting regulation is associated with the concept of "New Governance."[63] This concept involves promoting more shared responsibility and power between regulators and regulated entities.[64] According to some scholars, such shared responsibility and power would permit different groups to collaborate with each other, sometimes in shifting alliances, to negotiate solutions to complex problems as they arise.[65] Other advocates of this shared responsibility see it as a means of promoting experimentation in both rule-making and enforcement, which could reduce the cost of verification and compliance.[66] Regardless of the theoretical justifications for it, the New Governance approach to regulation focuses on three aspects: solving practical problems rather than vindicating abstract principles; permitting more fluid regulatory structures; and making enforcement a matter of persuasion more than punishment.[67]

One of the defining elements of the New Governance approach to regulation is the idea that it is better to solve problems through collaboration with the persons and entities who are subject to regulation, especially when such collaboration permits experimentation.[68] As one commentator explains:

> Such an approach is necessary because problems have become too complex for government to handle on its own, because disagreements exist about the proper ends of public action, and because government increasingly lacks the authority to enforce its will on

62. Carle, *supra* note 60, at 325.

63. Baer, *supra* note 23, at 1000-15.

64. *See, e.g.*, AYRES & BRAITHWAITE, *supra* note 55, at 86-87; Michael C. Dorf & Charles F. Sabel, *A Constitution of Democratic Experimentalism*, 98 COLUM. L. REV. 267 (1998); Jody Freeman & Daniel A. Farber, *Modular Environmental Regulation*, 54 DUKE L.J. 795, 860 (2005); Bradley C. Karkkainen, *Information as Environmental Regulation: TRI and Performance Benchmarking, Precursor to a New Paradigm?*, 89 GEO. L.J. 257 (2001); Orly Lobel, *The Renew Deal: The Fall of Regulation and the Rise of Governance in Contemporary Legal Thought*, 89 MINN. L. REV. 342 (2004); Lester M. Salamon, *The New Governance and the Tools of Public Action: An Introduction*, 28 FORDHAM URB. L.J. 1611 (2001); William H. Simon, *Solving Problems vs. Claiming Rights: The Pragmatist Challenge to Legal Liberalism*, 46 WM. & MARY L. REV. 127 (2004); Jason Solomon, Book Note, *Law and Governance in the 21st Century Regulatory State*, 86 TEX. L. REV. 819 (2008).

65. Dorf & Sabel, *supra* note 64, at 267; Simon, *supra* note 64, at 127.

66. AYRES & BRAITHWAITE, *supra* note 55, at 3-4.

67. Dorf & Sabel, *supra* note 64, at 267; Simon, *supra* note 64, at 127.

68. Salamon, *supra* note 64, at 1623.

other crucial actors without giving them a meaningful seat at the table.[69]

Under a New Governance approach, the regulators and regulated entities are involved in a dialogue to reached shared objectives, and the regulated entities are granted significant discretion to devise processes necessary to achieve those goals.[70] As William Simon has contended, by focusing on problem-solving as the core objective of regulation, the New Governance approach emphasizes "common interests, rather than the notion connoted by the idea of rights of individual interests competing with group interests."[71] This kind of collaboration and discretionary action promotes an atmosphere of trust, in which both public and private actors can feel freer to fully disclose relevant information and assure that the regulatory system is constantly adapting to meet new realities in the regulated field.[72]

The collaborative process at the heart of New Governance regimes means that regulators and regulated entities will work together to determine performance goals for the entity, as well as the procedural mechanisms by which those performance goals will be accomplished.[73] This means that the regulators are in a better position to assess the viability of the assumptions underlying regulatory objectives.[74] Collaboration also gives regulators a tangible stake in assuring that performance objectives and procedural mechanisms will work in the real world occupied by the regulated entity.[75]

The collaborative approach to New Governance regulation also involves a reduction in the severity of formal sanctions, especially for firms that initially fail to reach prescribed standards.[76] Lesser and initial violations are met with efforts at persuasion and consultation by the regulators.[77] If the corporation's violations are egregious and repetitive, more punitive measures can be employed.[78] In addition, some proponents of New Governance have also called for the creation of new forms of sanctions, including social control sanctions, such as "re-in-

69. Salamon, *supra* note 64, at 1623.

70. Baer, *supra* note 23, at 1002; Bamberger, *supra* note 42, at 377-78; Salamon, *supra* note 64, at 1673.

71. Simon, *supra* note 64, at 178; Baer, *supra* note 23, at 1004.

72. Lobel, *supra* note 64, at 462; Baer, *supra* note 23, at 1002.

73. AYRES & BRAITHWAITE, *supra* note 55, at 106; Baer, *supra* note 23, at 1003.

74. Baer, *supra* note 23, at 1003.

75. AYRES & BRAITHWAITE, *supra* note 55, at 106; Baer, *supra* note 23, at 1003.

76. Lobel, *supra* note 64, at 395; Baer, *supra* note 23, at 1004.

77. Baer, *supra* note 23, at 1005.

78. *Id.*

tegrative shaming."[79] The objective of these new forms of sanctions is to "indu[ce] guilt and responsiveness in the wrongdoer" unlike punitive sanctions, which are much more likely to "induce anger and resistance," which can be obstacles to on-going compliance.[80]

Given the rhetoric with which it is typically presented, it would be easy to see the New Governance approach as a kind of utopian ideal.[81] After all, who could be against collaboration, problem-solving, and increased trust between government agencies and those that regulate them? But such a dramatic departure from established approaches to regulation cannot be expected to happen overnight, with the dissemination of some law review articles and some meetings between corporate officers and the administrators of regulatory agencies.[82] Indeed, there is a kind of chicken-and-egg problem with shifting to a New Governance regime. Collaborative problem-solving and the granting of discretion cannot work without a high level of trust between the regulators and the regulated; but trust cannot exist without a history of collaboration.[83]

C. *Combining the Positive and Negative Aspects of Compliance*

All of this shows that, like any new theory, the New Governance attempts to re-conceptualize an existing field; and, as with other new and largely untested theories, it is not clear whether and to what extent the New Governance approach will be workable. But there is much to recommend the idea of focusing compliance programs on showing managers, employees, and agents how to internalize the goals of the law and make them their own.[84] One reason to promote such internalization is that it is consistent with a sophisticated idea of corporate personhood, one that recognizes the corporation as something more than a profit-maximizing machine.[85]

It is, of course, commonplace to conceptualize the corporation as a purely economic actor that exists only to create profits for its shareholders and that responds only to the values of the marketplace.[86] According to the finance theory taught in business schools, the idea of

79. Ayres & Braithwaite, *supra* note 55, at 92.
80. *Id.*
81. *See id.*
82. Baer, *supra* note 23, at 1006-07.
83. *Id.*
84. *See e.g.*, Larry D. Thompson, *The Responsible Corporation: Its Historical Roots and Continuing Promise*, 29 Notre Dame J. L. Ethics & Pub. Pol'y 199 (2015).
85. *Id.* at 201-05.
86. *See* Milton Friedman, Capitalism and Freedom 133 (40th ed. 2002).

profit maximization "does not mean . . . a *primarily* monetary interest, a *primary* concern for economic growth, more income, fewer costs. It means truly 'maximization,' a sole concern for profit."[87] One of the most notable proponents of this viewpoint is the Nobel Laureate Milton Friedman, whom insisted that a corporation has "one and only one social responsibility . . . – to . . . increase its profits . . . ."[88] Indeed, according to Professor Friedman, it would "undermine the very foundations of our free society" if corporations recognized and acted upon any "social responsibility other than making maximum profits for stockholders" as possible.[89] He posited that any suggestion that a corporation should respond to something other than the profit motive is "a fundamentally subversive doctrine."[90] If the corporation is viewed through Professor Friedman's economistic lens, then corporate compliance with the law can only be understood as a constraint on corporate action because compliance has no capacity to contribute to increasing the bottom line on the corporate balance sheet.[91] Under this view, compliance merely involves additional costs that diminish profits, and corporations should comply with the law only to the extent necessary to avoid costly legal sanctions.[92]

However, there are good reasons to reject this purely economic viewpoint.[93] Human beings have created Corporations to serve human needs.[94] As one commentator put it, "'[b]usiness' is not a set of value-free machines. 'Business' is a set of living human organizations allowing us as individuals to live in a way we can stand to live – to have lives as individuals we can justify to ourselves and each other."[95] Human beings do more than merely calculate profits; they act in service of substantive values other than profit-making.[96] Human beings

87. Thompson, *supra* note 84, at 202 (quoting Joseph Vining, *The Effect of Economic Integration with China on the Future of American Corporate Law* 1, (Univ. of Mich. Law Sch. Scholarship Repository: Law & Econ. Working Papers, Paper No. 11, 2010), https://repository.law.umich.edu/cgi/viewcontent.cgi?article=1122&context=law_econ_current). (emphasis in original).

88. FRIEDMAN, *supra* note 86, at 133.

89. *Id.*

90. *Id.*

91. Thompson, *supra* note 84, at 202.

92. *See id.* at 202-03.

93. *See id.* at 201-05 (arguing against the purely economic conception of the corporation promoted by Prof. Friedman).

94. *Id.* at 202, 202-03.

95. Joseph Vining, *Competition, Corporate Responsibility and the China Question*, 45 L. QUADRANGLE NOTES 83, 88 (2003), http://repository.law.umich.edu/cgi/viewcontent.cgi?article=1097&context=other.

96. *See id.* at *88.*

do not refrain from taking actions that could harm others simply because such actions would be costly; they refrain from actions with harmful consequences because "[w]e actually don't want someone else to be hurt, and if we really don't care, and really are indifferent to the consequences of our actions, we are viewed as a bit of a psychiatric case and a threat—certainly not someone who can be dealt with in ordinary affairs."[97] Given this unavoidable fact about human beings and the institutions they create, it seems anomalous to conceive of the corporation as being solely directed to profit-maximization.[98]

The case of Enron provides an object lesson in the dangers of an exclusive concern with profit-maximization.[99] Enron had a state-of-the-art corporate code of conduct, reflecting a single-minded devotion to profit maximization, that led to "the ascendance of *unenlightened* self-interest—winning for yourself; I win, you lose. The Enron . . . rationalization was, 'We didn't do anything wrong, because we didn't break the law.'"[100] Eventually, of course, Enron did break the law in manifold ways, and this result was the consequence of a corporate culture that was devoted to profits at the exclusion of all other values.[101]

One reason that disaster resulted from Enron's single-minded devotion to profit is that Enron overlooked the human dimension of the corporation. Larry Thompson, former officer with Monsanto and Providian Financial Corporation, and a former United States Deputy Attorney General, explained the problem with the view of the corporation as an entity entirely devoted to profit:

> The shortcoming of this view is that the corporation is not solely an economic phenomenon – it is a legal phenomenon as well. A business corporation does not rise spontaneously from the intersection of contracts among private parties in the marketplace. A corporation is a legal fiction – an artificial person "existing only in intendment and consideration of law," and we create these artificial persons in our own image. We are social and moral actors with responsibilities to our community – why should we assume that our corporations are not? They have whatever characteristics we endow them with and whatever responsibilities we choose to impose on them. A corporation has perpetual life; it governs itself through bylaws of its own choosing, it can buy and sell property and can sue and be sued in its own name – and, in law, its liability is limited to the assets that it holds in its own name. A corporation possesses

97. Vining, *supra* note 95, at 83.

98. *See id.* at 88; *see also* Thompson, *supra* note 84, at 202-03.

99. Vining, *supra* note 95, at 85.

100. Lenny T. Mendonca & Matt Miller, *Interview with Daniel Yankelovich, Public Opinion Analyst & Social Scientist, in La Jolla, Cal.*, 2 McKinsey Q. 64, 2007, 69.

101. Thompson, *supra* note 84, at 202-03.

> these attributes only because the state has willed that it be so. It is therefore more than a little strange to suppose that a body corporate owes nothing to the body politic that created it as an act of legislative grace.[102]

As Thompson points out, the corporation should consider non-economic objectives for another reason; because it has been created by law and must respond to the underlying principles that animate the law, as well as the explicit legal rules that prescribe certain aspects of corporate conduct.[103] In other words, the corporation cannot operate entirely according to economic principles because it is not the product of solely economic forces.[104] According to economic theory, considerations relevant to social interests are considered to be "externalities," which should not be factored into the corporation's assessment of costs and benefits.[105] However, the law, not economic theory creates the corporation, and it is the law, not economic theory, that decides what is external and what is internal to the corporation.[106]

Scholars are not the only ones who reject absolute allegiance to Friedman's idea that the corporation can properly be devoted to profit-making alone.[107] In its Principles of Corporate Governance, the American Law Institute ("ALI") has provided that, in the conduct of its business, a corporation has no legal obligation to pursue profit alone and "[m]ay devote a reasonable amount of resources to public welfare, humanitarian, educational, and philanthropic purposes."[108] Indeed, the ALI recognizes that such pursuit of non-economic objectives is appropriate "[e]ven if corporate profit and shareholder gain are not thereby enhanced."[109] Similarly, the Business Roundtable eschews a purely economic conception of the corporation and recognizes that corporations have a duty to serve social needs, along with the interests of their shareholders in profit-making.[110]

Given that many corporations operate internationally, American authorities are not the only relevant ones in determining

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102. Thompson, *supra* note 84, at 202-03 (quoting 1 WILLIAM BLACKSTONE, COMMENTARIES *464).

103. *Id.* at 203-05.

104. *Id.* at 203-05; *see also* Vining, *supra* note 95, at 84.

105. Vining, *supra* note 95, at 84.

106. Thompson, *supra* note 84, at 203-05.

107. *See* PRINCIPLES OF CORPORATE GOVERNANCE: ANALYSIS AND RECOMMENDATIONS, § 2.01(b) (AM. LAW INST. 1994).

108. *Id.*

109. *Id.*

110. Statement of the Business Roundtable, *Corporate Governance and American Competitiveness*, 46 BUS. LAW. 241, 244 (1990).

fundamental principles of corporate governance, especially the objectives that the corporation should serve. For example, in Japan, a court held that the chemical company was liable for the birth defects caused by the company's discharge into a bay of waste water which contained mercury.[111] The company's discharge did not violate any environmental law; it was in compliance with every statutory and regulatory standard.[112] Indeed, the company's methods for treating its waste water were state of the art and were superior to the methods pursued by similarly situated companies.[113] The company was liable because it had acted in a manner that was contrary to a social interest.[114] China mandates similar corporate attention to social interests.[115] To be sure, China's concern with socially conscious corporate behavior could be seen as a product of its Communist heritage; its former corporation law made business firms responsible for "strengthening socialist spiritual civilization."[116] However, even after China embraced market capitalism, it still expressly requires that a corporation "respect" and act in furtherance of "social responsibility."[117] Consequently, international corporations have an even greater reason to establish governance principles that account for something more than profit.[118]

A corporation cannot effectively internalize social goals if it views compliance strictly as a matter of acting within a constraint imposed by law.[119] The kinds of objectives that are not comprehended by economic theory are more easily achieved when viewed as internal to the corporation and not simply as externalities that restrict profitability.[120] Because a goal is defined from within the corporation (unlike a constraint, which is defined by something outside the corporation), it can be more effective to view compliance as a goal rather than a constraint.[121]

Moreover, viewing adherence to the law as the achievement of a goal rather than as accession to a constraint can make for more effec-

111. *See* Vining, *supra* note 95, at 85-86.
112. *Id.*
113. *Id.*
114. *See id.*
115. Vining, *supra* note 95, at 6 (comparing the 1993 and 1999 Companies Law of the People's Republic of China).
116. *Id.*
117. *Id.*
118. *Id.*
119. *See id.* at 84.
120. Vining, *supra* note 95, at 84.
121. *Id.*

tive compliance.[122] This is particularly true when the regulatory scheme is open-ended and applies to discretionary decision-making by corporate actors.[123] When a regulation does not create a black-letter rule but, instead, demands the thoughtful application of abstract principles, compliance training will be much more effective when it facilitates the internalization of those principles by corporate actors.[124] The following section will show how the federal regulatory scheme prohibiting false claims and kickbacks in the provision health care services creates just the abstract and flexible system that resonates with the insights behind New Governance ideas of compliance.

II. The Federal Regime for Preventing Fraud and Kickbacks in Health Care Services

The provision of health care services entails a risk that decisions about treatment will be made by what is profitable rather than what is medically necessary.[125] This is especially true when physicians are considering whether to refer a patient to another health care provider.[126] In this situation, it is important that the medical professionals place the patient's interest ahead of any considerations about their mutual business advantage.[127]

To reduce the possibilities of such self-interested decision-making, the federal government has imposed a broadly framed statutory prohibition against the payment of kickbacks in connection with the provision of any medical service associated with a federal health care program.[128] According to the Department of Justice's Office of Inspector General ("OIG"), the purpose of this prohibition "is to protect patients and the federal health care programs from fraud and abuse by curtailing the corrupting influence of money on health care decisions."[129] Given the breadth of this prohibition, Congress authorized the OIG to promulgate regulations defining certain "safe harbors"—categories of conduct that will not implicate the Anti-Kickback stat-

122. Vining, *supra* note 95, at 84; *see also* Thompson, *supra* note 84, at 201-05.

123. *See* Vining, *supra* note 95, at 84; *see also* Thompson, *supra* note 84, at 201-05.

124. Vining, *supra* note 95, at 84.

125. *See, Fact Sheet: Federal Anti-Kickback Law and Regulatory Safe Harbors,* Office of Inspector Gen. (Nov. 1999), http://oig.hhs.gov/fraud/docs/safeharborregulations/safefs.htm [hereinafter *Fact Sheet*].

126. *Id.*

127. *Id.*

128. *See* 42 U.S.C. § 1320a–7b (2012).

129. Ayres & Braithwaite, *supra* note 55, at 86-87.

ute's prohibitions.[130] These regulatory safe harbors are essential in understanding how the Anti-Kickback statute applies to medical practice.[131]

Federal law provides additional protection against the abuses of medical decision-making through the False Claims Act ("FCA"), which prohibits the making of false statements in connection with any claim for payment from the federal government—for example, through a claim for reimbursement through a federal health insurance program.[132] Because much of the conduct that could violate the Anti-Kickback statute also involves false statements about what is medically necessary, there is substantial overlap between Anti-Kickback statute and the FCA with respect to health care providers.[133] Consequently, compliance efforts must look to both statutes when establishing the boundaries of acceptable conduct.

A. Anti-Kickback Statute

One of the key aspects of this federal regulatory regime is the prohibition against kickbacks between health care providers. The federal Anti-Kickback statute imposes criminal penalties on any person that "knowingly and willfully solicits, receives, offers, or pays any remuneration (including any kickback, bribe, or rebate) directly or indirectly, overtly or covertly, in cash or in kind," to any person:

> (A) in return for referring an individual to a person for the furnishing or arranging for the furnishing of an item or service for which payment may be made in whole or in part under a Federal health care program, or
>
> (B) in return for purchasing, leasing, ordering, or arranging for or recommending the purchasing, leasing, or ordering of any good, facility, service, or item for which payment may be made in whole or in part under a Federal health care program.[134]

The prohibition on kickbacks is quite broad.[135] It applies to essentially every proposed financial interaction, whether or not actually implemented, among health care providers and pharmaceutical companies.[136] In the first years after its enactment, the statute was often

130. AYRES & BRAITHWAITE, *supra* note 55, at 86-87.
131. See 42 C.F.R. Part 1001 (2017).
132. *See* 31 U.S.C. §§ 3729-3731 (2009).
133. *Compare* 42 U.S.C. § 1320a-7b (2015), *with* 31 U.S.C. §§ 3729-3731 (2012).
134. 42 U.S.C. § 1320a-7b(b)(1).
135. *See id.*
136. *See* Publication of OIG Special Fraud Alerts, 59 Fed. Reg. 65372 (Dec. 19, 1994).

interpreted to apply primarily to relationships between institutional providers or suppliers and practitioners in a position to generate referrals for the providers or suppliers.[137] However, in 1994, the OIG issued a fraud alert that made it clear that the statute applied to pharmaceutical marketing activities, including:

> Any prize, gift or cash payment, coupon or bonus (e.g., airline discounts and related travel premiums), offered to physicians and/or suppliers (including pharmacies, mail order prescription drug companies and managed care organizations) in exchange for, or based on, prescribing or providing specific prescription products. These items are particularly suspect if based on value or volume of business generated for the drug company.
>
> Materials which offer cash or other benefits to pharmacists (or others in a position to recommend prescription drug products) in exchange for performing marketing tasks in the course of pharmacy practice related to Medicare or Medicaid. The marketing tasks may include sales-oriented educational or counseling contacts, or physician and/or patient outreach, etc.
>
> Grants to physicians and clinicians for studies of prescription products when the studies are of questionable scientific value and require little or no actual scientific pursuit. The grants may nonetheless offer substantial benefits based on, or related to, use of the product.
>
> Any payment, including cash or other benefit, given to a patient, provider or supplier for changing a prescription, or recommending or requesting such a change, from one product to another, unless the payment is made fully consistent with a safe harbor regulation.[138]

There is some uncertainty about the *mens rea* requirement for the Anti-Kickback Statute; the statutory text does not define the terms "knowing and willfully," and the Federal Courts of Appeals are split on the definition.[139] Some courts have held that the violator must have had the specific intent to violate the anti-kickback statute itself.[140]

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137. Publication of OIG Special Fraud Alerts, 59 Fed. Reg. 65372.

138. *Id.* at 65376.

139. *Compare* United States v. McClatchey, 217 F.3d 823, 829 (10th Cir. 2000) (requiring a specific intent to violate the statute); *and* Hanlester Network v. Shalala, 51 F.3d 1390, 1400 (9th Cir. 1995) (requiring that a defendant know the requirements of the statute and "engage in prohibited conduct with the specific intent to disobey the law"); *with* United States v. Starks, 157 F.3d 833, 838 (11th Cir. 1998) (using a standard set of jury instructions for the term "willfully" and requiring knowledge of unlawful conduct, as opposed to knowledge of violating the specific statute); *and* United States v. Jain, 93 F.3d 436, 440-41 (8th Cir. 1996) (requiring only that a defendant know the conduct was wrongful, rather than knowledge that the conduct violated a known legal duty).

140. *See, e.g.*, *McClatchey*, 217 F.3d at 829; *Hanlester Network*, 51 F.3d at 1400.

Others have set a slightly lower bar for finding *mens rea*, holding that a defendant can be liable under the statute as long as the defendant knows its conduct is wrongful, even if it does not know the specific law that makes it wrongful.[141] Despite this division of opinion of just how specific an accused's intent must be, there is no doubt that the statute requires a specific intent to engage in wrongdoing as a basis for liability.[142]

The statute does carve out certain areas of activity that are exempt from the broad statutory prohibition.[143] These "safe harbors" are set forth in both the statutory text itself, and in regulations established by the OIG.[144] The safe harbors describe activities that the government will not prosecute because the government has determined that these activities are unlikely to be abusive.[145] The safe harbors are more likely to apply to price concessions provided in connection with the purchase of drugs or the purchase of expert consulting services, than to promotional or other activities that provide "one-sided" value to customers and consumers.[146]

In addition to the formally defined exceptions and safe harbors, there are other ways that particular instances of conduct can escape the anti-kickback statute's broad prohibition.[147] An arrangement among health care providers and/or pharmaceutical companies that would, on its face, violate the statute may be deemed lawful by the OIG if it does not involve improper intent or does not adversely affect the quality of patient care.[148] The OIG has described certain "aggravating considerations" that identify those arrangements that may pose the greatest risk of prosecution.[149] Those considerations include:

> Does the arrangement or practice have a potential to interfere with, or skew, clinical decision-making? Does it have a potential to undermine the clinical integrity of a formulary process? If the arrangement or practice involves providing information to decision-makers, prescribers, or patients, is the information complete, accurate, and not misleading?

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141. *See, e.g.*, *Starks*, 157 F.3d at 838; *Jain*, 93 F.3d at 440-41.
142. *See, e.g.*, *Starks*, 157 F.3d at 838; *Jain*, 93 F.3d at 440-41.
143. *See Fact Sheet*, *supra* note 125.
144. *Id.*
145. *Fact Sheet*, *supra* note 125.
146. *Id.*
147. *See* OIG Compliance Program Guidance for Pharmaceutical Manufacturers, 68 Fed. Reg. 23731, 23736 (May 5, 2003).
148. *Id.*
149. *See id.*

> Does the arrangement or practice have a potential to increase costs to the federal health care programs, beneficiaries, or enrollees? Does the arrangement or practice have the potential to be a disguised discount to circumvent the Medicaid Rebate Program Best Price calculation?
>
> Does the arrangement or practice have a potential to increase the risk of overutilization or inappropriate utilization?
>
> Does the arrangement or practice raise patient safety or quality of care concerns?[150]

A recent Seventh Circuit case illustrates the challenges in assuring compliance with the requirements of the anti-kickback statute.[151] Because the statute raises delicate factual questions about the intent of participants in a transaction and the effect of that transaction on their medical decisions, health care providers must take care not only in framing the details of any particular transaction itself, they must also look to circumstances surrounding that transaction.[152] Compliance with the Anti-Kickback statute can be assured only by being sensitive to their actions and the attendant contexts for those actions.[153]

In *United States v. Patel*, the defendant was an internist who treated many elderly patients who needed home care services and paid for those services with Medicare benefits.[154] When Dr. Patel determined that one of his patients needed home care services, his staff provided the patient with brochures from numerous companies that provided such services and permitted the patient to make an independent choice among them.[155] One provider, Grand Home Health Care, offered to pay Dr. Patel for referrals.[156] According to Dr. Patel's trial testimony, he never affirmatively accepted this offer and continued to follow his existing method of informing his patients about many home healthcare providers and allowing them to make independent choices.[157] As it happened, somewhere between two and four patients selected Grand each month.[158] When a patient selected Grand, Grand would create a treatment plan for the patient and fill out a Medicare

150. OIG Compliance Program Guidance for Pharmaceutical Manufacturers, 68 Fed. Reg. 23731, 23734 (May 5, 2003).
151. See United States v. Patel, 778 F.3d 607 (2015).
152. *Id.* at 615-18.
153. *See id.*
154. *Id.* at 609.
155. *Id.* at 610.
156. *Id.* at 609.
157. *Patel*, 778 F.3d at 609.
158. *Id.* at 610.

certification form 485 for Dr. Patel's signature, which is required for Medicare reimbursement.[159] Whenever Dr. Patel signed the certification form, Grand would give him $400, and it paid a further $300 for his signature on a recertification form, which was required after the first sixty days of treatment.[160] The payments were made in cash, with no written contract or other formal payment record.[161] There was no dispute that the patients needed the services; nor did the government allege that Dr. Patel directed their decision-making about which provider to choose.[162] And only a small minority of his patients used Grand.[163]

When the government began investigating Grand's business practices, Grand agreed to cooperate, and evidence was collected about the payments to Dr. Patel, among others.[164] Dr. Patel was charged with criminal violations of the Anti-Kickback statute, which entailed both substantial fines and imprisonment.[165] As a defense, Dr. Patel argued that he had not actually referred any of his patients to Grand because they had made their own independent decisions about their home health care providers.[166] He contended that "refer" means that the physician personally recommends that a patient seek care from a particular provider, and conversely that there is no "referral" when a patient independently chooses a provider.[167]

The Seventh Circuit rejected this interpretation of the statute.[168] It concluded that a physician provides a referral anytime that it acts as a gatekeeper for the patient's receipt of services.[169] In reaching this conclusion, the court invoked the statute's principal purpose, which is to prevent decision-making that leads to increased cost of care and contravention of patient free choice.[170]

Dr. Patel insisted that this kind of definition of "referral" would criminalize a wide range of innocent activities.[171] For example, if a hospital paid a physician to give a speech, Dr. Patel argued that this broad

159. Patel, 778 F.3d at 610.
160. Patel, 778 F.3d at 611.
161. *Id.* at 611.
162. *See id.* at 610.
163. *Id.*
164. *Patel*, 778 F.3d at 611.
165. *Id.*
166. *Id.*
167. *Id.* at 612-13.
168. *Patel*, 778 F.3d at 613.
169. *Id.* at 613-14.
170. *Id.* at 615.
171. *Id.* at 616.

definition could mean that such a physician could be liable if some of his patients are later treated by the hospital that paid for his speech.[172] The Court disagreed, noting two important points.[173] First, a payment must be "in return" for a referral to trigger the application of the statute; payments made solely as compensation for legitimate services (such as giving a speech) are not illegal.[174] Second, to be a "referral," the physician must do *something* that either directs a patient to a particular provider or allows the patient to receive care from that provider.[175] "And even if the doctor in Patel's hypothetical *had* steered his patients to the hospital, the doctor could not be prosecuted because he was not paid 'in return for' referrals."[176]

The *Patel* case shows that both physicians and other health care providers must be sensitive to all aspects of their business relationship in order to avoid a risk of liability under the Anti-Kickback statute.[177] The government views patient referrals in a broad context, and everyone with any connection to a patient referral must be aware of all aspects of that context to assure that no-one takes any actions that could be construed as violations.[178] This means that any person connected in any way to a health care referral must have a comprehensive understanding of the general principles of the statute and must be always prepared to apply that understanding.[179]

B. False Claim and Fraud Laws

Federal law also prohibits health care providers from submitting false information in connection with claims for government payments, such as Medicare or Medicaid reimbursement.[180] This prohibition comes from laws of general application, such as the statutes that make it a crime to make false statements to the government or to make false or fraudulent statements in connection with the delivery or payment of healthcare services.[181] But the federal statute most directly applicable to health care services is the Federal False Claims Act

172. *Patel*, 778 F.3d at 617.
173. *Id.*
174. *Id.*
175. *Id.* at 618.
176. *Id.* (emphasis in original).
177. *See Patel*, 778 F.3d. at 614-17.
178. *See id.*
179. *See id.*
180. 18 U.S.C.A. § 1001 (West 2006); 18 U.S.C.A, § 1035 (West 2017).
181. 18 U.S.C.A. § 1001; 18 U.S.C.A. § 1035.

("FCA").[182] A person may be subject to penalties under the FCA for knowingly submitting a false claim for payment to the federal government (or for causing another person to submit such a false claim).[183]

Like the Anti-Kickback statute, the FCA requires a high level of *mens rea* for liability.[184] For the purposes of the statute, "knowing" or "knowingly" means that a person: (1) "has actual knowledge of the information on which the claim for payment is made"; and (2) "acts in deliberate ignorance of the truth or falsity of the information"; or, "acts in reckless disregard of the truth or falsity of the information."[185] Unlike the Anti-Kickback statute, however, the FCA does not require a specific intent to defraud or act wrongfully.[186]

FCA claims may be brought by the government or by private parties, who act as whistleblowers in a *qui tam* action.[187] In general, a *qui tam* action is one in which the whistleblower, known in technical terms as a "relator," makes a claim on behalf of the government.[188] The enforcement of the FCA through *qui tam* actions has increased in frequency in recent years.[189]

The remedies available to FCA plaintiffs, including relators, can be extensive. For one thing, the FCA provides for mandatory treble damages.[190] After the judge or jury determines actual damages at trial, the court must apply mandatory treble damages.[191] In addition, the FCA provides for mandatory civil penalties of $5,500 to $10,000 for each and every individual claim that is identified at trial.[192] In *qui tam* actions, the relator may be awarded as much as thirty percent of the recovery on claims where the government does not intervene and up to

182. See 31 U.S.C.A. § 3729 (West 2009); 31 U.S.C.A. § 3730 (West, 2010) 31 U.S.C.A 3731(West, 2009).

183. 31 U.S.C.A. § 3729(a).

184. 31 U.S.C.A. § 3729(b).

185. 31 U.S.C.A. § 3729(b)(1)(A).

186. 31 U.S.C.A. § 3729(b)(1)(B) (providing the knowledge requirement in the FCA "require[s] no proof of specific intent to defraud").

187. 31 U.S.C.A. § 3730(b)(1) ("A person may bring a civil action for a violation of section 3729 for the person and for the United States Government. The action shall be brought in the name of the Government. The action may be dismissed only if the court and the Attorney General give written consent to the dismissal and their reasons for consenting."); *see also* 31 U.S.C.A. § 3730(c).

188. 31 U.S.C.A. § 3730(c).

189. *See generally* Amandeep S. Sidhu, *The Growing Threat of Qui Tam Litigation Against Health Care Providers*, 12 A.B.A SEC. LITIG. 1 (2014), http://www.mwe.com/files/Publication/9594f763-6360-4b78-af86-04b9dc36c045/Presentation/PublicationAttachment/7b9ab237-b52c-4104-82a1-4eb3db00c5d3/Sidhu.pdf.

190. 31 U.S.C.A. § 3729(a)(1)(G).

191. *Id.*

192. *Id.*

twenty-five percent of the recovery on claims where intervention doe occur.[193] Finally, the losing defendant may have to pay the relator' attorneys' fees and other litigation costs.[194]

Amendments to the FCA were effected as a part of the enact ment of the Patient Protection and Affordable Care Act[195] ("ACA") i 2010. These amendments established four significant changes to th FCA that favored relators and increased the extent of potential liabil ity for health care providers.[196]

First, the amendments limited the availability of an often-use defense in *qui tam* cases under the FCA.[197] Before the ACA, court were required to dismiss an action when the factual basis for the rela tor's claims had been publicly disclosed.[198] But, the ACA amendment limited the circumstances under which public disclosure would lead t dismissal, and it provided that, even when public disclosure occurred the government could preserve jurisdiction over the case by objectin to the motion to dismiss.[199] Second, the ACA revised the requiremen to provide relators with a lower threshold of knowledge necessary t overcome the limitation on actions affected by public disclosure.[20 While the prior statutory language required relators to have "direc and independent knowledge of the information on which the allega tions are based," the amendments modified the requirement so tha they need only have "knowledge that is independent of and materiall adds to the publicly disclosed allegations or transactions."[201] Third, a a supplement to earlier amendments that had been part of the 200 Fraud Enforcement and Recovery Act, the ACA added a sixty-day re tention rule for overpayments that could give rise to FCA liability.[20 After the ACA amendments, providers were required to report and re turn any overpayments within sixty days of discovery or be subjecte to potential FCA liability.[203] Fourth, the ACA resolved a circuit spli

193. 31 U.S.C.A. § 3730(d).

194. 31 U.S.C.A. § 3730(d)(4).

195. Patient Protection and Affordable Care Act, Pub. L. No. 111-148, 124 Stat. 11 1025 (2010) (codified at 42 U.S.C. ch. 47).

196. *Id.*

197. *See* 31 U.S.C.A. § 3730(e)(4)(A) (West 2005).

198. *Id.*

199. 31 U.S.C.A. § 3730(e)(4)(A).

200. 31 U.S.C.A. § 3730(e)(4)(B).

201. *Id.*

202. *See* Fraud Enforcement and Recovery Act of 2009, Pub. L. 111-21, 123 Stat. 161 31 U.S.C. §§ 3729; 42 U.S.C. § 1320a-7k (as added by the Patient Protection & Affordabl Care Act, Pub. L. 111-148, effective Mar. 23, 2010).

203. *Id.*

regarding whether claims submitted as a result of violations of the anti-kickback statute constitute false claims for purposes of FCA liability.[204] With the ACA amendments, providers now face automatic statutory liability under the anti-kickback statute.[205]

Because the FCA can have surprisingly extensive application, it is essential that all employees and agents of health care providers be sensitive to its requirements. This point is clearly illustrated by the Supreme Court's recent decision in *Universal Health Services Co. v. United States ex rel. Escobar*.[206] There, a young woman from a poor family was diagnosed with bipolar disorder and received a prescription for medication.[207] Medicaid paid for her treatment.[208] Over the course of several months, she suffered repeated seizures from the medication, eventually dying from complications due to the seizures.[209] When her parents became concerned that the treatment was not effective, they complained to state regulators, who discovered that the treatment providers were both unqualified and unsupervised.[210] When the company who had referred the treatment providers was charged under the False Claims Act, the question arose whether that company had made a false certification.[211] Specifically, there was a question about the extent of knowledge about the treatment that was required to trigger FCA liability; the defendant company argued that it did not have direct knowledge that unqualified persons were providing treatment and therefore that the claim for Medicaid reimbursement was false.[212]

In a unanimous decision, the Court held that failing to disclose non-compliance with a statutory, regulatory, or contractual requirement could render a claim false or fraudulent (thereby validating the "implied false certification" theory of liability); however, the Court nonetheless imposed a "demanding" standard on plaintiffs to demonstrate that the omission was both relevant and important.[213] Because Universal Health Services had submitted claims to Medicaid using specific billing codes that misrepresented the qualifications of their

204. *See* 42 U.S.C. § 1320a-7b (h) ("With respect to violations of this section, a person need not have actual knowledge of this section or specific intent to commit a violation of this section.").

205. 42 U.S.C § 1320a-7b(g).

206. Universal Health Serv's v. U. S. *ex rel.* Escobar, 136 S. Ct. 1989 (2016).

207. *Id.* at 1997.

208. *Id.*

209. *Id.*

210. *Id.*

211. *Universal Health Serv's*, 136 S. Ct. at 1997.

212. *Id.* at 1998-99.

213. *Id.* at 1999-2002.

workforce, and because the underlying regulatory violations were substantial, the Court suggested that the plaintiff-relator had met its legal burden.[214] In particular, the Court pointed to the statute's reference to reckless disregard of the truth as a basis for liability, thereby imposing a substantial burden on any person or company who submits claims for payment from government health insurance programs.[215]

This holding means that health care providers cannot avoid FCA liability by disregarding the factual circumstances underlying treatment.[216] They will be required to take an active role in assuring the propriety of any services paid for by the government.[217] Thus, their employees and agents will have to be vigilant about taking an active role in understanding all aspects of the treatment process.[218]

III. The Application of the Anti-Kickback Statute and the FCA to Specific Types of Transactions in the Provision of Health Care Services

Given the breadth of the prohibitions imposed by the Anti-Kickback statute and the FCA, there are a wide variety of situations that can implicate either or both of these statutes in the provision of health care services. In order to understand the principles that should inform the development of an effective compliance program, it is necessary to understand some of the most prominently discussed situations and how they can be handled without violating either the Anti-Kickback statute or the FCA. The following section describes some of those situations.

A. Drug and Device Sales

The rules prohibiting kickbacks create a special challenge for the sales of any drug or medical device because they create a risk that any discount offered on a sale could be characterized as a remuneration paid in return for the purchase of the product.[219] In addition, because of the intersection between the FCA and the Anti-Kickback

214. *Universal Health Serv's*, 136 S. Ct. at 1999-2002.

215. *Id.* at 2001.

216. *Id.* at 2002.

217. *See id.* at 2001-02.

218. *See id.*

219. *See* 42 U.S.C. § 1320a-7b(b)(1) (2015) (defining a "kickback" as "remuneration" paid in return for "purchasing, leasing, ordering, or arranging for or recommending [the] purchasing, leasing, or ordering of any good, facility, service, or item for which payment may be made in whole or in part under a Federal health care program").

statute, improperly offering or providing a discount that is characterized as a kickback could lead to FCA liability as well.[220] Thus, the need for effective compliance precautions is particularly important whenever any seller of health care products or services contemplates offering some kind of discount.

Because discounts can be a perfectly legitimate instrument of fair competition in the marketplace, the regulatory scheme surrounding the Anti-Kickback statute creates a safe harbor exception for discounts.[221] This safe harbor protects discounts on items and services reimbursed under a federal health care program.[222] For the purposes of the statutory scheme, "discount" is defined as a reduction in the amount a buyer is charged for an item or service based on an arms-length transaction.[223] "Discount" includes rebates and other discounts not given at the time of sale.[224] The definition excludes all of the following: (1) cash payments or equivalents; (2) supplying one good or service without charge or at a reduced charge to induce the purchase of a different good or service unless both are reimbursed by federal health care programs pursuant to the same methodology (i.e., the same global payment); (3) a reduction in price applicable to one payer but not to federal health care programs; (4) a routine reduction or waiver of any coinsurance or deductible amount: (5) warranties; (6) services provided in accordance with a personal or management services contract; or (7) other remuneration not explicitly defined as a discount.[225]

In its official guidance regarding how to comply with the statutes and regulations prohibiting kickbacks, the OIG emphasized that:

> any remuneration from a manufacturer provided to a purchaser that is expressly or impliedly related to a sale potentially implicates the anti-kickback statute and should be carefully reviewed . . . . Examples of remuneration in connection with a sale include, but are not limited to, "prebates" and "upfront payments," other free or reduced-price goods or services, and payments to cover the costs of "converting" from a competitor's product.[226]

Given that the line between permissible discounts and impermissible kickbacks can be so difficult to draw, it is essential to identify particu-

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220. 42 U.S.C. § 1320a-7b(b)(1).
221. 42 C.F.R. § 1001.952(h) (2017).
222. *See* § 1001.952(h).
223. § 1001.952(h)(5).
224. § 1001.952(h)(4).
225. § 1001.952(h)(5).
226. OIG Compliance Program Guidance for Pharmaceutical Manufacturers, 68 Fed. Reg. 23731, 23735-36 (May 5, 2003).

lar factors that will be important in the distinction that the regulatory authorities will make.[227]

According to guidance from the OIG, the crucial factor in distinguishing between legitimate and illegitimate discounts is whether the price reduction effected by the discount was a part of the sales transaction.[228] In its guidance, the OIG has emphasized that the discount must be in the form of a reduction in price given at the time of sale or set at the time of sale.[229] When a benefit of some kind is defined and provided after the sales transaction, it is impermissible to characterize such a benefit as a "discount" on an earlier transaction.[230]

Apart from the time at which the discount is defined and promised, there are other factors that can help identify discounts that qualify for the safe harbor.[231] Many of these factors are specific to certain kinds of transactions. For example, discounts must be disclosed on invoices or similar documentation.[232] In addition, the buyer must be put on notice of its obligation to report the discount; and nothing must be done to impede that buyer from fulfilling its obligations.[233] Because full disclosure of pricing arrangements is essential for fostering full and fair competition, pharmaceutical manufacturers must also track and report discounts accurately under various government pricing programs, many of which require that the price reported include all applicable discounts.[234]

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227. *See* OIG Compliance Program Guidance for Pharmaceutical Manufacturers, 68 Fed. Reg. at 23735-36.

228. OIG Compliance Program Guidance for Pharmaceutical Manufacturers, 68 Fed. Reg. at 23735.

229. *Id.*

230. *See id.*

231. *Id.*

232. *Id.*

233. OIG Compliance Program Guidance for Pharmaceutical Manufacturers, 68 Fed. Reg. at 23735.

234. *See, e.g.*, 42 U.S.C. §1396r-8 (2016) (providing that, as a part of the Medicaid Drug Rebate Program, a manufacturer must report price data on a quarterly basis to the Centers for Medicare & Medicaid Services, including the "best price" for each drug, which includes any discounts); 42 U.S.C. § 1395w-3a (2011) (providing that, as a part of Medicare Part B, manufacturers must make quarterly reports of the "average sales price" for each drug covered under Medicare Part B for all purchasers in the United States and that the calculation of the sales price includes all discounts and rebates); 38 U.S.C.§ 8126 (1997) (providing that manufacturers must make covered outpatient drugs available to certain federal agencies, such as the Department of Veterans Affairs, the Public Health Service, the Department of Defense and the Coast Guard, at discounted prices, known as the "federal ceiling price," which is determined on the basis of disclosures about the prices, including discounts, that the manufacturer offers to private parties).

Certain kinds of methods for offering price reductions and inducing business create particular problems for the discount/kickback distinction.[235] For example, in some situations, sellers try to win new customers and encourage an initially high volume of business by providing "upfront payments" and/or "signing bonuses."[236] Such payments generally apply to first-year purchases, and they are defined when the seller establishes a net price for each purchase during the first year, which varies with the number of purchases.[237] The OIG generally views such payments as suspect, and they are difficult to conform to the "discount safe harbor" unless the payments are applied to specific purchases.[238]

Similarly, when a seller offers a credit memo as a substitute for a cash discount, it may run afoul of the reporting requirements because the credits may be earned based on the purchase of certain products, but, are applied to reduce the purchase price of other products.[239] When a transaction involves a discount framed as a credit memo, any agreement between the buyer and seller should clearly identify the credit as a discount, and the agreement should clearly set forth the allocation of the discount, so there will be no doubt that the discount was framed and applied at the time of the transaction.[240]

Another circumstance that can lead to problems under the Anti-Kickback statute and/or the FCA arises when a manufacturer offers free supplies and equipment that are incidental but necessary to the use of the product that the manufacturer makes and sells.[241] In many cases, these incidental supplies and equipment have no independent value because they are connected with the use of the manufacturer's product.[242] Whether the provision of these incidental items at no cost constitutes a discount depends upon the nature of such items, and both manufacturers and sellers can be in a quandary about how to allocate the value of such free equipment to other purchases.[243] Along similar

235. *See* D. McCarty Thornton, *OIG Letter on Upfront Rebates, Prebates, and Signing Bonuses*, OFF. OF INSPECTOR GEN. (July 17, 2000), http://oig.hhs.gov/fraud/docs/safeharborregulations/prebate.htm.

236. *Id.*

237. *See id.*

238. *See id.*

239. *Id.*

240. *Id.*

241. *See e.g.*, Kevin G. McAnaney, *OIG Letter on Free Computers, Facsimile Machines, and Other Goods*, OFF. OF INSPECTOR GEN. (July 3, 1997), http://oig.hhs.gov/fraud/docs/safeharborregulations/freecomputers.htm.

242. *See id.*

243. *See id.*

lines, manufacturers may offer free product support or reimbursement assistance to physicians or other providers by providing information regarding insurance coverage criteria and reimbursement levels for their products.[244] These services have no independent value to providers apart from the products themselves.[245] In these cases, the incidental support services may be considered part of the products purchased, and their cost may be considered bundled into the products' prices.[246] But, other reimbursement support programs may look more like impermissible kickbacks because they represent an independent financial benefit to physicians or other providers.[247] These reimbursement services might include requiring payment for products by purchasers only if the product is reimbursed by third party payors.[248] According to the OIG, these services eliminate the normal financial risks for providers and create overutilization and increased costs.[249]

Another potential problem associated with the sale of medical devices involves demonstrations and training provided by the manufacturer.[250] Unlike drugs, a complicated medical device may require a demonstration to evaluate the device or training to ensure its appropriate use.[251] Most commonly, the manufacturer itself will provide such demonstrations or training, and, in many cases, the manufacturer will offer them at a central location, such as the manufacturer's own facility or at the site of a professional meeting, but not at the facility of each and every health care provider that might be interested in the device.[252] When a manufacturer hosts these activities, the manufacturer may reimburse physicians or other provider representatives for the reasonable costs of travel and lodging related to attendance at training sessions.[253] But, in this context, both buyers and sellers have to be careful to avoid covering excessive travel or lodging costs (which could

244. OIG Compliance Program Guidance for Pharmaceutical Manufacturers, 68 Fed Reg. 23731, 23735 (May 5, 2003).

245. *See id.*

246. *See id.*

247. OIG Compliance Program Guidance for Pharmaceutical Manufacturers, 68 Fed Reg. at 23735.

248. *See id.*

249. *See id.*

250. ADVANCED MEDICAL TECHNOLOGY ASSOCIATION, CODE OF ETHICS ON INTERACTIONS WITH HEALTH CARE PROFESSIONALS 11-12 (2009), https://www.advamed.org/sites/default/files/resource/112_112_code_of_ethics_0.pdf.

251. *Id.*

252. *See id.* at 16.

253. *See id.* at 16.

make the demonstration seem like an excuse for a vacation for the buyer's representatives).[254]

B. *Sales of Services*

Of course, the flow of transactions between health care providers and drug and device makers flows in both directions. Manufacturers may purchase a wide range of services from the institutions that provide health care, as well as the doctors and other professionals associated with the provider. Doctors and professionals can provide these services by acting as advisory board members, speakers, preceptors, or researchers.[255] Anytime a manufacturer purchases services from a person who is a customer or is associated with a customer, one can question whether the manufacturer's purchase is merely a cover for an unlawful kickback. And, if the purchased service implicates a claim for a payment from the federal government in one way or another, there could be questions about FCA liability as well. Both manufacturers and health care providers must be careful to assure that all arrangements for services to manufacturers are commercially reasonable and should avoid any suggestion of excessive or improper payments to the professionals providing the services.

As with other kinds of transactions between manufacturers and health care providers, the provision of professional services to manufacturers must come within one of the defined safe harbors.[256] The safe harbor for personal services and management contracts protects certain arrangements.[257] To qualify for safe harbor protection, personal service, and management contracts between health care providers and manufacturers must meet certain conditions:

- there must be a formal, written agreement that is signed by both parties;
- the agreement must cover all of the services to be provided for the term of the agreement;
- the agreement must be for at least one year;
- if the agreement provides for the services on a periodic, sporadic or part-time basis, the agreement must specify exactly the sched-

254. *See* ADVANCED MEDICAL TECHNOLOGY ASSOCIATION, *supra* note 250 at 16.

255. The purchase of research services from provider institutions and their employees will be discussed more fully in *infra* Section III.C in connection with the sponsorship of clinical trials. *See infra* Section III.C.

256. OIG Compliance Program Guidance for Pharmaceutical Manufacturers, 68 Fed. Reg. 23731, 23736 (May 5, 2003).

257. *Id.*

ule of such intervals, their precise length, and the exact charge for such intervals;

- the aggregate compensation paid to the agent over the term of the agreement must be set in advance and be consistent with fair market value in arms-length transactions, and must not be determined in a manner that takes into account the volume or value of any referrals or business otherwise generated between the parties for which payment may be made in whole or in part under Medicare or a state health program;
- the services performed under the agreement must not involve the counseling or promotion of a business arrangement or other activity that violates any state or federal law; and
- the aggregate services contracted for must not exceed those which are reasonably necessary to accomplish the commercially reasonable business purpose of the services.[258]

Some of these conditions can be difficult to accomplish. For example, the realities and uncertainties of an evolving business arrangement can make it difficult, and perhaps impossible, for the manufacturer and the health care provider to anticipate exactly how and when all of the services will be provided. Consequently, it is often difficult to meet the requirement that aggregate compensation be set in advance and the requirement that periodic services be provided according to a set schedule. But, all is not lost if a compensation arrangement cannot meet the conditions for the safe harbor exception. A compensation arrangement may nevertheless be permissible if it sets forth in writing a method for precisely calculating a payment per unit of service.[259] Thus, if an arrangement establishes in advance a specific payment for each hour of advisory board service or an honorarium for each speaking engagement, it may survive scrutiny.[260] As the OIG pointed out in its guidance literature:

> In general, fair market value payments to small numbers of physicians for *bona fide* consulting or advisory services are unlikely to raise any significant concern. Compensating physicians as "consultants" when they are expected to attend meetings or conferences primarily in a passive capacity is suspect. Also of concern are compensation relationships with physicians for services connected directly or indirectly to a manufacturer's marketing and sales activities, such as speaking, certain research, or preceptor or "shadowing" services. While these arrangements are potentially beneficial, they also pose a risk of fraud and abuse. In particular, the use of health care professionals for marketing purposes—in-

258. *See* OIG Compliance Program Guidance for Pharmaceutical Manufacturers, 68 Fed. Reg. 23731 (May 5, 2003).

259. *Id.* at 23738.

260. *Id.*

> cluding, for example, ghost-written papers or speeches—implicates the anti-kickback statute. While full disclosure by physicians of any potential conflicts of interest and of industry sponsorship or affiliation may reduce the risk of abuse, disclosure does not eliminate the risk. . . . . Recently, some entities have been compensating physicians for time spent listening to sales representatives market pharmaceutical products. In some cases, these payments are characterized as "consulting" fees and may require physicians to complete minimal paperwork. Other companies pay physicians for time spent accessing web sites to view or listen to marketing information or perform "research." All of these activities are highly suspect under the anti-kickback statute, are highly susceptible to fraud and abuse, and should be strongly discouraged.[261]

C. Clinical Trial Sponsorship

The makers of drugs and medical devices also engage the professionals employed by their customers when it comes to conducting research for their products. The research may be designed to generate the clinical data required for FDA approval of a new product or new indication for an existing product, or the research may be necessary to generate clinical data used as a basis for marketing programs for a product that has already been approved by the FDA. Clinical trial sponsorship will raise concerns under the Anti-Kickback statute to the extent that the clinical trial has no meaningful value to the manufacturer or that the compensation paid to the principal investigator/health care provider for conducting the trial exceeds the fair market value of the services provided.[262]

The OIG has set forth some basic principles governing the sponsorship of clinical trials. It has pointed out that:

> Manufacturers often contract with purchasers of their products to conduct research activities on behalf of the manufacturer on a fee-for-service basis. These contracts should be structured to fit in the personal services safe harbor whenever possible. Payments for research services should be fair market value for legitimate, reasonable, and necessary services. Post-marketing research activities should be especially scrutinized to ensure that they are legitimate and not simply a pretext to generate prescriptions of a drug. Prudent manufacturers will develop contracting procedures that clearly separate the awarding of research contracts from marketing. Research contracts that originate through the sales or

261. OIG Compliance Program Guidance for Pharmaceutical Manufacturers, 68 Fed. Reg. at 23738.

262. *Id.* at 23735-36.

> marketing functions—or that are offered to purchasers in connection with sales contacts—are particularly suspect.[263]

Clinical trial sponsorships also entail FCA considerations.[264] Because more health care providers may be billing Medicare for services provided in the context of a clinical trial, there is an increased risk that clinical trial sponsorship may implicate the FCA.[265] Clinical trial sponsorship by manufacturers may also implicate the FCA if the trial involves claims to government payors when: (1) the services are not Medicare covered services, or (2) the services are Medicare-covered services, but the sponsor has paid for the services.[266] The risk is also enhanced where payment by commercial or governmental sponsors under the clinical trial agreement is not linked to specific costs.[267] This enhances the importance of making sure that any clinical trial agreements clearly set forth costs and charges in advance to the greatest extent possible and that all charges for any services are commercially reasonable.[268]

D. Grants

Manufacturers often provide grants to promote scientific, educational, or community service objectives.[269] When those grants are provided to entities, organizations, or individuals who are affiliated with their customers, there is a risk that the provision of the grant could be characterized as a quid pro quo for a business opportunity and, therefore, as a kickback.[270] And in some cases, the benefit to the grantor may be something as intangible as goodwill, which has real, albeit hard-to-quantify, economic value.[271] Of course, the social benefits derived from grants give regulatory authorities strong incentives to

263. OIG Compliance Program Guidance for Pharmaceutical Manufacturers, 68 Fed. Reg. at 23735-36.

264. *See* OIG Supplemental Compliance Program Guidance for Hospitals, 70 Fed. Reg. 4858 (Jan. 31, 2005).

265. *See id.*

266. *Id.* at 4858-59.

267. *See id.*; *see also National Coverage Determination on Medicare Coverage in Clinical Trials*, CTRS. FOR MEDICAID AND MEDICARE SERVICES, (July 9, 2007), https://www.cms.gov/medicare-coverage-database/details/ncd-details.aspx?NCAId=248&NcaName=Intensive+Behavioral+Therapy+for+Cardiovascular+Disease&ExpandComments=y&ver=2&NCDId=1&ncdver=2&bc=BEAAAAAAEEAAAA%3D%3D&.

268. *Id.*

269. *See* OIG Compliance Program Guidance for Pharmaceutical Manufacturers, 68 Fed. Reg. at 23735.

270. *Id.*

271. *See id.*

avoid leaping to the conclusion that a grant is, in fact, a kickback that should give rise to sanctions.[272] In this way, grants create a paradox for regulators because government enforcement agencies have acknowledged that a for-profit company may provide funding to third parties (including parties other than charitable organizations) even though there is no direct, measurable benefit to the manufacturer other than the promotion of goodwill.[273] Government enforcement agencies, however, expect that the manufacturer can demonstrate that the grant is a legitimate grant and not a disguised discount or other inducement.[274]

The provision of a grant may implicate the anti-kickback statute where the grant benefits an individual or entity who is in a position to influence the prescription or purchase of products.[275] Such a grant could be construed as a disguised inducement for the recipient to use or to promote the use of a manufacturer's products.[276] For example, such an interpretation could be appropriate where a "grant" is provided to cover a routine expense the customer would otherwise incur or substitute for a product discount because such "grants" are not really grants.[277]

The OIG has offered guidance on how grantors and recipients can avoid any suggestion of conduct that would violate the Anti-Kickback statute in connection with the provision of a grant.[278]

> To reduce the risks that a grant program is used improperly to induce or reward product purchases or to market product inappropriately, manufacturers should separate their grant making functions from their sales and marketing functions. Effective separation of these functions will help insure that grant funding is not inappropriately influenced by sales or marketing motivations and that the educational purposes of the grant are legitimate. Manufacturers should establish objective criteria for making grants that do not take into account the volume or value of purchases made by, or anticipated from, the grant recipient and that serve to ensure that the funded activities are bona fide. The manufacturer should have no control over the speaker or content of the educational presenta-

272. *See id.*
273. *See* OIG Compliance Program Guidance for Pharmaceutical Manufacturers, 68 Fed. Reg. at 23735.
274. *See id.*
275. *See id.*
276. *See id.*
277. *See id.*
278. *Id.*

tion. Compliance with such procedures should be documented and regularly monitored.[279]

Grants also provide another occasion when conduct that implicates the Anti-Kickback statute can also implicate the FCA.[280] Grants may implicate the FCA to the extent that they are perceived as disguised discounts.[281] To minimize the risk of violating either the Anti-Kickback statute or the FCA, grant activities should be insulated from sales and marketing activities.[282] In this connection, there several important safeguards that can be taken to assure compliance.[283]

First, potential grantors should make sure that they are not using grants to obtain new customers or reward existing customers.[284] Thus, funding should not be conditioned upon the purchase of a product.[285] A manufacturer may wish to further separate grant-giving from its business relationships by making information about grants generally accessible, such as by posting information on its website and by encouraging applications from any qualified person, not just from those associated with the manufacturer's market targets.[286] Readily accessible information avoids a situation in which the only way an individual or institution could find out about available grant funds was through contact with a sales representative who is seeking to initiate, maintain or reward a customer relationship.[287]

Second, the activity funded by the grant should meet established criteria uniformly applied to assess similar activities.[288] For example, research funded should meet objective scientific criteria.[289] To establish that the grant was provided in accordance with these criteria, grantors should retain policies or other documentation regarding eligibility requirements for grants and the application/approval process.[290]

279. OIG Compliance Program Guidance for Pharmaceutical Manufacturers, 68 Fed. Reg. at 23736.

280. *Id.*

281. OIG Compliance Program Guidance for Pharmaceutical Manufacturers, 68 Fed. Reg. at 23734-35.

282. *Id.* at 23736.

283. *See id.*

284. *Id.*

285. *Id.*

286. *Id.*

287. *See id.*

288. OIG Compliance Program Guidance for Pharmaceutical Manufacturers, 68 Fed. Reg. at 23736.

289. *Id.*

290. *Id.*

Third, to further assure that the grant is clearly distinguished from the grantor's ordinary business transactions, the funding should not be offered in lieu of a discount or to otherwise provide value to a customer.[291] Consequently, the grantor's sales representatives should not be the source of information about grants, nor should they promise grants or otherwise indicate that grants will be provided to fund a particular activity, even if the activity meets all criteria for an award.[292] Decisions about awarding grants should be made prior to the activity and not after the activity to fill funding gaps.[293] In short, grants should not subsidize the routine business operations of the customer.

Fourth, the grant must actually be a grant. Manufacturers should have no control over the conduct of the activity.[294] Manufacturers should not influence the protocol or other aspects of research, nor determine the content of the educational program.[295] Along the same lines, the grant funds should be in a reasonable amount for the purposes specified in the grant, and they should actually be used for those purposes.[296] If there are surplus funds after the grant activity is complete, such a surplus should be returned to the manufacturer or, with the approval of the manufacturer, applied to similar activities.

E. Educational Activities

Academic medicine presents a problem similar to that arising in connection with the provision of grants. Because they provide both education to students and medical treatment to patients, medical schools and their affiliated hospitals are customers for the manufacturers of drugs and medical devices as well as providers of valuable information.[297] Thus, when a manufacturer provides financial support for a medical school's research or educational activities, it could be simply providing support for those activities, or it could be soliciting business through what amounts to a kickback.[298] The OIG advises that:

> While educational funding can provide valuable information to the medical and health care industry, manufacturer grants to purchas-

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291. *Id.*

292. *See* OIG Compliance Program Guidance for Pharmaceutical Manufacturers, 68 Fed. Reg. at 23736.

293. *Id.*

294. *Id.*

295. *Id.*

296. *Id.*

297. *See* OIG Compliance Program Guidance for Pharmaceutical Manufacturers, 68 Fed. Reg. at 23736.

298. *Id.*

> ers, GPOs, PBMs and similar entities raise concerns under the anti-kickback statute. Funding that is conditioned, in whole or in part, on the purchase of product implicates the statute, even if the educational or research purpose is legitimate. Furthermore, to the extent the manufacturer has any influence over the substance of an educational program or the presenter, there is a risk that the educational program may be used for inappropriate marketing purposes.[299]

The distinction between promotional activities in an academic setting and purely academic activities is also important in the context of regulations imposed by the Food and Drug Administration ("FDA").[300] The FDA distinguishes between (1) educational activities (programs and materials) performed by, or on behalf of, manufacturers; and (2) activities, supported by manufacturers, that are otherwise independent of the promotional influence of the supporting manufacturer.[301] Programs in the first category are subject to the FDA prohibition on off-label promotion.[302] For example, speakers in speaker programs held by the manufacturer must have presentations that affirmatively address only approved uses.[303] Speakers may only respond directly to unsolicited questions about off-label uses.[304] By contrast, truly independent and non-promotional activities are not subject to FDA regulation, even if they receive financial support from a manufacturer of drugs or medical devices.[305]

Continuing medical education ("CME") presents a set of related compliance problems. When manufacturers provide financial support for CME, there can also be questions about whether the support is truly aimed at educating practicing physicians or at winning their business.[306] The organization that provides accreditation for CME, the Accreditation Council for Continuing Medical Education ("ACCME"), offers support that will help solve these compliance problems and prevent violations of the Anti-Kickback statute.[307] ACCME standards

299. *Id.*

300. *See* generally Food and Drug Administration (FDA) Guidance for Industry: Industry-Supported Scientific and Educational Activities, 62 Fed. Reg. 64093 (Dec. 3, 1997).

301. *Id.* at 64094.

302. Industry-Supported Scientific and Educational Activities, 62 Fed. Reg. at 64095.

303. *Id.* at 64097.

304. *See id.*

305. *Id.*

306. *See Standards for Commercial Support: Standards to Insure Independence in CME Activities*, Accreditation Council for Continuing Med. Educ., http://www.accme.org/requirements/accreditation-requirements-cme-providers/standards-for-commercial-support (last visited Apr. 4, 2016) [hereinafter *Standards for Commercial Support*].

307. See *id.*

seek to ensure that all CME activities by accredited providers are independent, free of commercial bias, and beyond the control of commercial sponsors.[308] These standards impose several important disclosure requirements designed to avoid any appearance of impropriety.[309] First, these disclosure requirements apply to anyone involved in developing any of the content for CME programs, as well as the spouses or domestic partners of persons involved in such development.[310] Second, any form of financial support must be disclosed, regardless of whether the support comes is monetary or in-kind.[311] Third, a manufacturer cannot be a joint sponsor of any CME activity along with the organization or entity that is providing the CME program.[312] Fourth, when a CME provider does receive some form of financial support from a manufacturer, the provider must provide extensive and accurate documentation of the use of the funds to assure transparency.[313]

In addition to all of these considerations, there are also rigorous standards for dealing with conflicts of interest. The ACCME standards prescribe that, with respect to conflicts of interest, the mere disclosure is not enough to eliminate any impermissible commercial bias; the ACCME requires that any conflicts of interest arising from be eliminated entirely or controlled through the implementation of peer review safeguards.[314] Depending upon how the conflict of interest provisions are ultimately applied, institutional providers and affiliated physicians may have their CME involvement limited.[315] The risk associated with funding of educational programs that involve off-label discussions, including CME programs, can be further reduced if: (1) a manufacturer provides funding to programs that receive support from a number of manufacturers; and (2) a manufacturer provides funding to a number of educational providers (to avoid any suggestion that an educational provider is dependent upon the manufacturer and will cater to the manufacturer in developing content).[316]

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308. Standards for Commercial Support, *supra* note 306.
309. *Id.*
310. Standards for Commercial Support, *supra* note 306.
311. *Id.*
312. *Id.*
313. *Id.*
314. *Standards for Commercial Support*, *supra* note 306.
315. *Id.*
316. *Id.*

F. Charitable Donations

The potentially sweeping effect of the Anti-Kickback statute is so great that even a "charitable donation"[317] creates some risk of being characterized as a kickback. Of course, many health care providers, such as hospitals or physician groups associated with academic medical centers, are also considered charitable organizations.[318] Manufacturers may be solicited for donations because providers will often look to members of the community or business partners in seeking donations as these individuals or organizations are familiar to the provider. For their participation, manufacturers also have significant incentives for promoting research, education, and community service activities through charitable contributions. Problems may arise if the donee is also a customer of a manufacturer and if there is any suggestion that the donation is being offered or solicited as a quid pro quo for the continuation of the business relationship between the donor and donee.[319] Here again, avoiding liability under either the Anti-Kickback statute or under tax law depends upon assuring that the charitable character of the donation is confirmed by independent documentation. The persons involved in both paying and receiving the donation should not be the same individuals who are involved in making the decisions about buying and selling in the commercial dimension of the relationship.

Conclusion

It is no easy task to develop a compliance program for health care services. In particular, one that is well-adapted to the often open-ended requirements of the Anti-Kickback statute and the FCA. Because the business relationships in health care services are often complicated, involving multiple relationships in different contexts between the same two parties, there are few bright-line rules that always apply and are easily communicated to managers, employees, and agents.

The absence of bright-line rules makes it difficult for health care corporations to pursue the adversarial approach to compliance.

317. A charitable contribution is a donation of funds to a charitable organization (an organization determined by the Internal Revenue Service to be tax-exempt under 26 U.S.C. § 501(c)(3) as a contribution that supports the charitable purposes of the organization.

318. *"Public Charities"*, IRS, https://www.irs.gov/charities-non-profits/charitable-organizations/public-charities (last visited Mar. 2, 2018).

319. *See generally* OIG Compliance Program Guidance for Pharmaceutical Manufacturers, 68 Fed. Reg. 23731, 23735-36 (May 5, 2003).

Viewing the law as an external constraint and taking an adversarial approach to compliance means that corporations will try to keep their conduct as close to the boundaries of the law as possible, minimizing both their costs and the extent of their compliance. If there are no clear rules to follow, however, it is difficult or impossible for a corporation and its employees and agents to have confidence that their chosen course of action is going to skirt the edges of illegality. When the requirements of the law are murky, there is substantial risk that an official from an enforcement authority might view something as illegal, even if the corporation thinks that it is lawful. Consequently, with respect to the Anti-Kickback Statute and the FCA, it is difficult to rely on the adversarial approach to compliance programs.

The problems with the adversarial approach make an argument for viewing compliance as a goal rather than a constraint, at least in the field of health care services. Because those statutes impose vague rules, employees and agents cannot be sure of the legality of their conduct unless they have internalized the operative principles behind the statute and engaged in the process of trying to apply those principles in every situation. This kind of approach is exactly what is involved in treating compliance as an internal goal rather than an external constraint. The health care services field creates a powerful example of how and why it can be better to view compliance as a goal rather than a constraint.

This does not mean that it will be easy to make compliance a goal rather than a constraint. As a practical matter, it is impossible to apply the New Governance approach to the health care context because there is no single agency (or even a small group of agencies) who are responsible for enforcement and with whom health care providers can engage in dialogue. Indeed, because a great deal of enforcement authority is effectively delegated to private parties who can bring *qui tam* actions that the government may or may not choose to join, health care providers can never really know where the enforcement action is coming from and therefore can never know exactly how to collaborate with the enforcing authority.

But, even if a pure form of the New Governance approach is not a practical reality for improving compliance programs in the health care industry, the concepts behind New Governance still have much to offer those responsible for developing compliance programs that have to address the fluid requirements of the Anti-Kickback statute and the FCA. One of the crucial aspects of the New Governance paradigm is the idea that compliance programs should be founded upon the communication of fundamental legal and ethical principles and of methods

that individual employees can use to make sound judgments about lawful conduct in the absence of black-letter rules.[320] Perhaps most importantly, the New Governance approach involves training employees to internalize certain legal guidelines, so that they think of compliance as a goal rather than an externally imposed constraint.[321] If a compliance program cultivates the idea that the Anti-Kickback statute and the FCA are purely constraints on employee action and that complying with those statutes involves rote rule-following behavior, compliance will be manifestly imperfect because employees will inevitably find themselves in novel situations where the existing frameworks for applying the law do not clearly apply. By contrast, if compliance focuses on communicating core principles and developing independent judgment, employees will be far better prepared to deal with the ever-shifting factual circumstances in which they must apply the law.

In this respect, it will be essential for health care compliance programs to emphasize the collaborative ethos of the New Governance approach in the relationship between internal counsel, the compliance officers, and the managers, employees, and agents who must carry out the day-to-day work of compliance. Those in charge of the compliance program must be in constant communication with employees to learn about new circumstances in which the law must be applied and to convey new information about the judicial decisions and other legal actions that reflect new directions in the law. This kind of communication and collaboration within the health care corporation itself is the key to assuring that companies always base their compliance efforts on the best information about both the law itself and the ever-evolving factual context in which the law must be applied.

To illustrate how useful it can be to build a compliance program around insights from the New Governance approach, consider the following example: a medical school and its associated hospital seek to hold an educational program for physicians at the hospital regarding developing research that shows new ways to use an existing drug. The FDA has not, however, approved these new uses; the program is designed to encourage further new research and to keep the hospital at the cutting edge of new treatment methods, but, it is not designed to show physicians how to exploit the new use in their practices. The manufacturer of the drug still enjoys patent protection and is eager to develop new uses, so it offers to sponsor the educational program by providing a grant to the presenters of the program and by establishing

320. *See, e.g.*, Salamon, *supra* note 64, at 1623; Lobel, *supra* note 64, at 462.
321. *See supra* Section I.B.

a fund that will fund new research efforts by hospital staff and/or medical school faculty and students. The fund will be administered by both the drug manufacturer and the medical school faculty, who will jointly decide on who will receive the research grants.

In this situation, there are three entities interacting: a hospital, its medical school, and a drug manufacturer. But, these interactions are not perfectly straightforward because they involve multiple roles for each participant. The hospital is acting as both a customer of the drug manufacturer and as a partner of the medical school in its educational mission. The medical school is acting primarily in furtherance of its non-profit educational mission, but its actions also have commercial value, and some doctors who are on both the medical school faculty and the hospital staff have a dual role as both educators and commercial actors. For its part, the drug manufacturer is acting both as a charitable contributor and as a commercial actor seeking to develop new business. When each of these three entities takes an action in connection with the educational program, it will have to be keenly aware of what particular role it is advancing with that action, and it will have to be especially careful to distinguish between commercial and non-profit actions.

None of this can be done unless the individual physicians and staff who are involved in the program are aware of the multi-faceted nature of their roles and the differing legal principles and rules that apply to each facet. And there is no way to construct a compliance program that can provide advance directives prescribing how each individual actor should conduct himself or herself in any particular situation. Instead of giving individuals a compliance "script" to follow, the compliance program for any of the entities involved in this example must provide individuals with a method for reasoning through the compliance problems on their own. And, just as important, an effective compliance program would give individuals a mechanism for engaging with compliance officers in an on-going dialogue about emerging problems and solutions.

Finally, there is another reason to view compliance as a goal rather than a constraint, and this reason is the most fundamentally important one of them all. The entities that deliver health care services have an inherent and inescapable obligation to serve the public interest. Because most of these entities are organized as non-profits, and because they are necessarily devoted to promoting health and well-being generally, they cannot be exclusively devoted to maximizing profit. They must pursue non-economic objectives, including and especially those defined by law. For this reason, it is not enough for them to view

compliance with the law as a constraint. Rather, such compliance must be internalized as a goal. And, to effectively accomplish this internalization, it is useful and important for health care entities to adopt elements of the New Governance approach.